

REMARKS

1. The following claims are in prosecution, Claims 1, 2, 5, 9 to 16, and 18 to 24. Claims 3 to 4, and 6 to 8 were previously canceled, and herein claims 10, 12 and 17 are cancelled. Claims 1, 2, 11, 19, and 24 have been amended to further clarify the invention and special aspects.

Before addressing the more specific concerns raised by the examiner a few preliminary points are worth expressing and emphasizing about the present invention. The invention goes to a novel, non-obvious method of enhancing physical entry of compounds/drugs into a patient through a normal unbroken stratum corneum. This method can then be used in conjunction with a number of treatments, cosmetic and medical, to enhance the results of these treatments or facilitate an alternative way of accomplishing them. This patent is not about permanent hair removal. The exact chemistry of the materials identified in the steps of the present inventive method are not critical. It is generally the physical properties of the materials referenced in this invention and the manipulation of the application area and them which define the novelty and non-obviousness of the invention. Applicants fervently request that examiner reread the specifications in light of this, and then address the amended claims and specific remarks below. We wish to thank examiner for his detailed and thoughtful presentation of his objections in the most recent action.

2. The Examiner rejected Claims 1-2 , 5, 9 to 16 and 18 to 24 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons noted on page 2, paragraph 2.

The Examiner states that there is no support in the disclosure of the twice application of said compound/drug (claim 1) or at the same time (claim 2).

Claim 1 has been amended to indicate that the swellable composition is applied after a 'mechanical' hair removal to a small area of skin. The compound/drug is not applied two times, but is only applied after the lumen is held open by the swellable composition.

The support for this claim is clearly within the text, and this amendment removes the rejection under 35 U.S.C. 112, first paragraph.

As to Claim 2, the swellable composition might likely not be the same as one used in

Claim 1. See page 7, lines 27 to 29.

3. Claims 1-2, 5, 9-16, and 18-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement as stated by the Examiner. Many of these points are minor deflections compared to the true invention as emphasized above, but time has been spent demonstrate out of context conclusions, mixed and at times contradictory positions and offer a semblance of reasons for applicants' believing this to be the case.

a. The Examiner notes, "nowhere in the specification one can find what swellable composition is applied."

The applicant disagrees with this conclusion. In that "swellable composition" is noted at: Page 5, line 24; line 27 ("The swellable composition can be polymers that are biodegradable, bioactive, encapsulated in microspheres or liposomes, and/or form microspheres." The implication being that the polymers may be encapsulated in microspheres or in liposomes.); Page 6, line 17; line 26; Page 7, line 4; Page 8, line 9; line 26, to Page 9, line 7; Page 10, line 19; Page 11, line 3; line 16; line 25; Page 12, line 1; line 17; Page 13, line 1; Page 16, line 7. All of these references occur in the specification with detailed explanation therein.

As to what "swellable composition" is applied, this is defined on Page 8, line 26 to Page 9, line 7. Reference is made to US patents and other patent documents. These references are incorporated by reference. For example, US Patent 5,770,229 clearly defines swelling polymer gels.

Applicant disagrees with this conclusion. The definition of "swellable composition" is given in the specification and reference is made to many patent documents. It is clear that this description is in fact sufficient because these references were incorporated by reference, meaning these teachings are considered a part of the disclosure.

The novelty of the present invention is the selection of swellable compositions of polymers or other materials which can be applied to unbroken skin to fill pores, recently exposed by the removal or partial removal of hair follicles in a small section of said skin and finally using the openings to admit compound/drugs for medical or cosmetic treatments. No one has thought to use swellable compositions to hold open pores for enhanced penetration of compounds/drugs into the body through hair follicles.

b. On page 3 of the office action, the Examiner has repeatedly asserted with

regard to the specification that applicant makes the statement that “substance is a form of liposomes” but this, in fact, was not stated by the Applicant. The Applicant stated, “In one preferred embodiment, the substance is a form of microspheres or liposome.” The Examiner has taken out of context this statement because the statement is made with respect to sizes, not compositions of the swellable compositions that are appropriate for opening up the hair follicle. This assertion by the applicant is clearly supported by the following statement, Page 9, line 4, in that, “As disclosed in ... formulations containing specific size ingredients may target compounds to follicles.” Therefore, the “substance is a form of liposomes” is certainly not correct and nothing more than an effort to twist the meaning of the words for the benefit of aligning “facts” to the rejection of the claims. The subsequent conclusion has merely been made to support the Examiner’s own theory: the liposome itself is a swellable composition. As stated in claim 13, said “swellable composition are polymers” and as stated in claim 18, “said polymers are encapsulated in liposomes.” and therefore, the clear meaning of this combination is that the swellable composition is not a liposome as claimed herein by the Examiner. The swellable composition is encapsulated in liposomes and it is the size of the liposomes that are critical to the invention, not that the liposomes are “swellable compositions” in and by themselves.

c. The Examiner further notes on page 3, “there is no EP patent with the number recited.” Applicant notes that in the Information Disclosure Statement provided, the publication number is seen on the **actual document** as EP 0375520 (which was attached to the original filing), not the one noted on page 9, line 3 of the specification or as shown on the listing of the IDS. The specification has been amended to correct this typographical error.

d. Again, the Examiner has misinterpreted the implication of reference US 6,287,549. The Examiner indicates that the microspheres if made from fatty substances such as fatty alcohols and triglycerides would be lipophilic compounds and that these are water repellants.

The Applicant refers to US Patent 6,287,549, Col. 3, line 51, to Col. 4, line 30. As clearly stated, “The microparticles comprising the chromophores may be dispersed in any medium ... The dispersing phase may be a hydrophilic or hydrophobic composition ...” Then the Examiner states, “These are lipophilic compounds (water repellants) ...” According to the MedlinePlus Dictionary, such compounds have an affinity to lipids. If in fact the microparticles are lipophilic they would have an affinity for lipids which would cause the microparticles to swell. This patent

then states that the microparticles in the dispersing medium may be applied with a solvent like water. See Col. 4, line 28. Therefore the use of water with the microparticles of lipophilic compounds is taught in contrast to the assertion by the Examiner that the “instant specification does not provide adequate guidance....”

e. In response to the following assertions by the Examiner, applicant presents information that would otherwise prove statements made by the applicant.

As to “swellable compositions”, pages 5 to 13 of the specification, the Examiner claims that “swellable polymers” are disclosed, but not swellable compositions.”

Again, the Examiner has taken out of context statements made. As stated on page 5, lines 27 to 28, for example, “The swellable compositions can be polymers that are biodegradable, bioactive, encapsulated in microspheres or liposome, and/or form microspheres.” The Examiner stated on page 4 of the office action that a “swellable composition” was not disclosed. As stated in a standard dictionary, a composition is a mixture of compounds. Clearly, polymers encapsulated in liposome would qualify as a composition and thus the Examiner’s assertion is not correct. As noted on page 8, lines 26 to 27, “The term ‘swellable composition’ relates to a composition containing specific kinds of substance which swells.” It is therefore respectfully asserted that the Applicant has, indeed, defined the very words of the invention and if a polymer in fact swelled then it would fall within this definition of “swellable composition” although in fact there is not a mixture of compounds. Also, the applicant has stated on page 8, line 28 to 29, “Examples of swellable composition ... are disclosed in U.S. patents No.”

For example, U.S. Pat. 5,770, 229 details “water swelling polymer gel.” The statement made on page 4 that “... gels and creams meaning that there is some water in the composition” is not correct as well as the following statements by the Examiner. See for example, U.S. Pat. 5,770,229. The assertions by the Examiner in this issue would make the application inoperable. The application requires that the swelling occur after application of the composition into the pores. See Claim 1, step c.

As to the comments of hydrophobicity or hydrophilicity, the examiner’s comments go beyond what is key to the present invention as noted in section 1 above. If after review in reply to this reply, the examiner continues to have some questions in this area, we will address them. We just point out that liposomal formulations of drugs are most often created to take a hydrophobic material and improve its solubility in blood, a primary aqueous solution.

Applicant, therefore, maintains that the § 112 rejections are moot or in error.

4. The Examiner rejected claims 1 to 2, 5, 9 to 16, and 18 to 24, under 35 U.S.C. 112, second paragraph, for the reasons noted in paragraph 5.

Claim 1 has been amended to clarify the application of the swellable composition, and the compound/drug.

The compound/drug is not only applied to the skin surface so that it can enter into the hair follicle lumen and thus enhance its penetration through an unbroken section of stratum corneum. It is unlikely that the compound/drug could only be applied to the follicle lumen. The compound/drug is applied topically to the skin so that the compound/drug will penetrate the lumen and eventually pass through into the dermis/epidermis.

Claim 10 has been canceled and therefore the rejection of the words noted on the top of page 6 is moot.

As to Claim 11, since it is merely an example, any compounds which can be considered photosensitizers for photodynamic therapy, such as derivatives of known photosensitizers or precursors which become photosensitizers within a patient, photosensitizers will suffice. Claim 11 has been so amended.

As to claim 12, claim 12 has been canceled.

5. Claims 1-2, 5, 9 to 16, 18, and 21 to 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sumian et al., '549, for the reasons noted in paragraph 7 on page 7 to page 8.

Sumian et al. teaches ways to remove hair or improve permanency of such removal by a mechanical technique. This is not the invention claimed nor described in the present invention. The present invention is a method of enhancing drug penetration through unbroken stratum corneum without the need of needles, or other means to span this natural skin barrier. The compounds so transferred are then available in the patient's body to do what ever they are intended to do. In general the present invention provides alternatives to the use of needles, mere patches, 'topical cream' or systemic methods to introduce the desired compound/drug into the patient. This is why the Examiner is in error when he claims that the "instant steps b and c are inherent in prior art", but in '549 the application of the composition into the hair follicles is described on Column 5, line 62, to Column 6, lines 3. There is no need for preventing the closure of the hair follicle since the microparticles travel down and around the hair shaft due to their

specific sizes. See Figures 1 to 5 of '549 and therefore this step c is not inherent since it is not required or even needed in '549. Further, there is no requirement in '549 to have a swellable composition. Indeed, '549 is not relevant to the enhanced delivery of a drug to the human body, for example, since '549 is merely interested in removing hair or preventing the regrowth of hair.

The present invention is certainly not obvious in view of '549, but initial steps of its method appear to partially overlap. The examination of the present invention against '549 appears to be based primarily upon hindsight reconstruction.

5. Claims 1-2, 5, 9 to 16, 18, and 21 to 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaefer by itself or in combination with '549, for the reasons noted in paragraph 8 on page 8.

Previous traverses are incorporated by reference.

Schaefer (US Patent 5,292,512) details a composition related to skin treatment such as acne. The composition is composed of microspheres with an active product therein. The solvent noted is related to get the active ingredient into the microspheres, not to swell the microsphere after the ingredient is in them. (Col. 4, lines 55 to 68.) The composition is applied to the skin and enters the pilosebaceous orifices. The microspheres must have a given range to enter into these orifices of 3 to 10 μm . The microspheres may be made of polymers and other materials noted on Col. 3, lines 21 to 47. The active products are noted on Col. 3, line 48 to Col. 4, line 15. The polymer material is not noted as a swellable composition on Col. 4, line 65, but rather that the polymer may be swelled to "produce microspheres in a gel form." This goes to describe a particular state for the composition to be applied, in gel form. Schaefer is an invention for the treatment of acne, which by definition means a material applied to the skin must penetrate to pilosebaceous sac to treat the acne. As contrasted with the present invention in Claim 1, Schaefer does not remove the hair in the application area and it does not apply a swellable composition for the purpose of holding opening the hair lumens for the infusion of chemicals therein. The swelling of the microspheres in Schaefer as stated in col. 4, lines 55ff deal with the method of getting the active ingredients into the microsphere from their solvent or a common solvent for both the active ingredient and the polymeric microsphere.

It is therefore asserted that Schaefer does not make the present invention obvious. As particularly noted in Schaefer, Claim 1, the microspheres are filled with at least one

pharmaceutical product. In the present invention, the swellable composition is applied to the hair follicle and then a compound/drug is applied. Since the swellable composition insures that the follicular channel is open, the drug composition is thus more likely to be absorbed across the skin's natural barrier.

6. Claims 1 to 2, 5, 9 to 16 and 18 to 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/48716, further in view of Li (US Patent 5,914,126) and/or Nakamura, 1980 for the reasons noted on Page 10 of paragraph 9.

Previous traverses are incorporated by reference.

Li et al. disclose the application of liposomes onto mice skin which was shaved and then covered to immobilize and to prevent evaporation. Col. 41, line 65, to Col. 42, line 5.

From the text, it is clear that the removal of hair was for the purpose of harvesting the skin for examination and also the band-aid was for the purpose of preventing removal and evaporation as noted. Col. 42, lines 1 to 13. Neither of these features were of concern in the present invention since the hair was removed to provide a site where better penetration of the compound/drug into a patient through the lumen and covering of the swellable composition was for increasing the force of expansion laterally to force the lumen to stay open after the hair is removed. In fact, Li et al. indicate "provides compositions and methods which are useful for the specific delivery of beneficial compounds to hair follicle cells to, for example, improve hair color or condition, prevent alopecia, or to stimulate hair growth." Col. 3, lines 27 to 31. Not for entry of compound/drugs into the patients epidermis/dermis.

Nakamura et al. disclose the use of a tape having a composition thereon basically a patch with delayed absorption of a composition through normal stratum corneum which is clearly different than the present invention. The removal of hair on the test mice was for improving the contact area for the tape on the composition on the skin. Neither of the features were of concern in the present invention as noted above.

Therefore, neither reference teach the method steps of the present invention of preventing the closure of the hair follicle for maintaining open access to the follicles. These are method claims, not device claims and are directed at different methods.

7. Claims 1 to 2, 5, 9 to 16, and 18 to 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaefer cited above, further in view of Li (US Patent 5,914,126) and/or Nakamura, 1980 for the reasons noted on Page 12 of paragraph 10.

Previous traverses are incorporated by reference.

Schaefer discloses the use of composition for topical application having microspheres of polymers, for example, of a particular diameter range so as to be able to enter into the hair lumen. An active material is placed on or in the microsphere. As noted earlier reference to swelling of the polymeric microsphere is in the description of a method to get the active ingredient into the microsphere. This is of little consequence or teaching in reference to the true objectives of the present invention as outlined above and described in the specification.

The relevant teachings of Li et al. and Nakamura et al. are noted above as well as the reasons why they are not applicable to the present invention.

The applicant maintains thusly that the rejections under 35 U.S.C. 103(a) are not correctly applied in that mere usages of similar words are taken to imply features that are not even discussed in the cited references and are merely used to generate statements that use hindsight reconstruction for applying these words to the present invention. The treatments disclosed and claimed therein were not about the those which are claimed and described in the present patent for the many reasons outlined above.

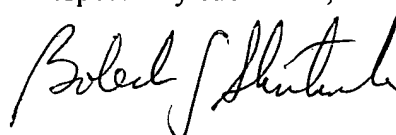
With these changes and remarks it is believed that the disclosure is now in condition for allowance. Reconsideration is respectfully requested. An early and favorable response is earnestly solicited. If necessary, a telephone call would be appreciated to discuss any further final changes to be made to render the claims allowable. Thank you.

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